

## **REMARKS**

This amendment is submitted in response to the Office Action mailed June 15, 2006 ("the Action"). Claims 1-53 are pending in the application. Claims 1-25, 29, 30, 34-40, 46-48, 50 and 53 are withdrawn from consideration by the Examiner as directed to non-elected inventions or species. Accordingly, Claims 1-25 have been canceled hereinabove without prejudice thereto. Claims 26-28, 31-33, 41-45, 49, 51 and 52 stand rejected.

### **I. The Specification Informality Objection**

Applicant has amended the informality in the paragraph on the first page of the specification as noted by the Examiner.

### **II. The 35 USC 112, Second Paragraph Rejection**

The Action states that Claim 42 recites a limitation without proper antecedent basis. Applicant has corrected this recitation hereinabove.

### **III. The 35 USC 102 Rejections**

The Action rejects Claims 26, 27, 41 and 42 as being anticipated by U.S. 5,772,613 to Gelfand et al. ("Gelfand")

The Action alleges that Gelfand teaches sensing "intrinsic spontaneous heart activity" of a patient in real time (citing to col. 9, lines 1-3) and compressing the chest using a vest based on the sensed activity which the Action opines is allegedly timed to a favorable time to improve cardiac function (col. 9, lines 3-10). Applicant respectfully disagrees. At col. 9, lines 3-10, Gelfand states that the heartbeat signal can be used by the timer control circuit to switch the valve to start vest inflation. Notably, Gelfand fails to teach or suggest timing the compression to avoid a vulnerable portion of the cardiac cycle. Indeed, Gelfand describes using pre-set/defined compression times and durations. For example, at, col. 8, lines 44-45, Gelfand states that the time of the compression period is pre-set in the control circuit, and may be about 400 ms. The pressure release stage of the vest is also stated to be a pre-set period such as 600 ms (col. 8, lines 55-56) and this preset period can be extended to 850 ms every fifth CPR cycle for ventilation of the patient (col. 8, lines 59-61).

In addition, Gelfand proposes monitoring a heartbeat signal using an ECG instrument, wherein the heartbeat signal is used to switch the valve to start vest inflation (col. 9, lines 1-10) a period of time following the QRS complex wave of the ECG signal to "coincide with the actual heartbeat" to assist a beating but weakened heart (col. 9, lines 7-10). However, Applicant submits that Gelfand is not discriminatory with respect to identifying a vulnerable portion of the cardiac cycle and timing the compression to avoid compressing the chest during a vulnerable portion of the intrinsic cardiac cycle.

Claims 26, 41 and 42 that are rejected as allegedly being anticipated by Gelfand are restated hereinbelow for ease of discussion.

26. A method for performing chest compression during cardiopulmonary resuscitation (CPR), comprising;  
sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR;  
identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject based on the sensed parameter; and  
compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac based on the identifying step thereby inhibiting reinduction of fibrillation and/or improving cardiac function.

41. A system for performing chest compression during cardiopulmonary resuscitation (CPR), comprising;  
means for sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR;  
means for electronically identifying a favorable time to compress the chest to avoid a vulnerable portion of a spontaneous intrinsic cardiac cycle of the subject based on the sensed parameter; and  
means for compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identified time.

42. A system for assisting in chest compression in a subject having cardiomalfuction, comprising:  
at least one cardiac activity sensor in communication with the heart of a subject configured to detect a cardiac activity parameter; and  
a controller in communication with the at least one cardiac activity sensor, wherein, in operation, the at least one cardiac activity sensor transmits data to the controller regarding a spontaneous intrinsic cardiac cycle of the subject and the controller identifies a favorable time to deliver

a chest compression based on the transmitted sensor data to avoid a vulnerable portion of the intrinsic cardiac cycle.

Applicant respectfully submits that Gelfand does not teach or suggest at least the emphasized features and requests that this rejection be withdrawn.

#### **IV. The 35 USC 103 Rejections**

##### **A. Claims 28 and 43**

The Action rejects Claims 28 and 43 as being obvious over Gelfand in view of U.S. Patent No. 6,198,968 to Prutchi et al. ("Prutchi"). More particularly, the Action concedes that Gelfand does not teach timing the compression so that it does not overlap with the T-wave portion of the intrinsic cardiac cycle as recited in Claims 28 and 43, but then opines that Prutchi discloses there is a vulnerable portion of the cardiac cycle (citing col. 3, lines 1-23). Thus, the Action concludes that Prutchi teaches avoiding stimulating during the T-wave. Thus, the Action alleges that one of skill in the art would have modified the system of Gelfand to avoid stimulation during the T-wave as taught by Prutchi "since application at this time may result in fibrillation of the heart" (Action, page 5). Applicant respectfully disagrees.

Prutchi is directed to an implantable cardiac pacer device and states that an ICD should avoid pacing the heart during the vulnerable "refractory period" in which cardiac tissue is not sensitive to electrical stimulation, as doing so may result in "reentrant tachycardia that may degenerate into fibrillation" (col. 3, lines 19-20). Prutchi is concerned with electrical stimulation for pacing and, if necessary, a defibrillation pulse. Prutchi is not directed to CPR techniques and Applicant respectfully submits that compressing the chest during CPR is very different than applying an electrical pulse with an implanted pacing device. One of skill in the art would not have combined the references in the manner alleged absent the teachings of the instant invention.

Further, controlling electrical stimulation with an implanted device during a vulnerable period is very different from identifying and controlling manual compression during CPR. The instant invention can time and alert a paramedic or clinician or other CPR provider when to start compression and when to stop compression (see, e.g., new Claims 54 -56) as discussed, for example, at page 7, lines 20-24 of the instant application.

Further, if the references were combined, Applicant submits that the device of Gefland would be modified to also include an electrical implant, and the electrical stimulus would be timed based on Prutchi. Applicant submits that one of skill in the art would not have modified the Gefland and Prutchi references in the manner alleged by the Action, absent the teachings of the instant application.

In view of the foregoing, Applicant respectfully submits that the claims are patentable over the cited references.

**B. Claims 31-33, 44 and 45**

The Action rejects Claims 31-33, 44 and 45 as being obvious over Gelfand in view of U.S. 6,390,996 to Halperin et al. ("Halperin"). The Action concedes that Gelfand is directed to vest compression rather than manual compression, but alleges that since manual compression is well known, as evidenced by Halperin, and that since Halperin proposes using closed chest manual compression based on sensed ECG patterns (col. 2, line 62- col. 3, line 17), it would have been obvious to substitute the manual compressions of Halperin for the automated vest compressions of Gelfand "in order to allow the therapy to be applied by hand quickly and without having to wait to apply the vest of Gelfand." Applicant respectfully disagrees.

First, Applicant respectfully submits that it is improper to select certain features from a prior art document disregarding the overall teachings of the document. Clearly, the very essence of Gelfand is a vest to carry out chest compression during CPR. Halperin is directed to manual and vest-applied (col. 10, lines 6-10) compressions during CPR using an ECG signal that (a) can be obtained with allegedly reduced artifacts that, in the past, were stated by Halperin to make ECG signal interpretation difficult (col. 3, lines 1-5) and (b) has a chest compression monitor to measure rate and depth of chest compression and to be able to signal when the correct compression is achieved (col. 9, lines 10-20). Applicant submits that one of skill in the art would not have modified Gelfand with Halperin, as Halperin clearly describes the use of both a vest type and manual type compression and there is no need to modify them in the manner alleged by the Action.

Further, even combined, Gelfand and Halperin do not describe monitoring cardiac status to identify a vulnerable portion of the intrinsic cardiac cycle as an aid in the delivery of the compression.

**C. Claims 32, 44 and 45**

The Action rejects Claims 32, 44 and 45 because Halperin uses an audible indicator for allegedly signaling "the correct time to apply compression" (Action, p. 6), citing col. 5, lines 60-65. The Action also states that Halperin discloses a monitor to display the real-time ECG of the patient "so that the physician may correctly apply compressions (col. 11, lines 50-58).

However, Halperin **DOES NOT** signal the correct time to apply compression; rather, Halperin signals when proper chest displacement is achieved (col. 9, lines 14-20). In addition, the ECG on the monitor is provided to ascertain a true ECG signal, not "so that a physician can correctly apply compressions" as alleged, and in particular not so that compressions can be timed to avoid a vulnerable portion of the cardiac cycle.

Thus, Applicant respectfully submits that Claims 32, 44 and 45 are patentable over the cited prior art.

**D. Claims 49 and 51**

The Action states that Claims 49 and 51 are obvious over Gefland. Applicant respectfully disagrees. Claim 49 recites, *inter alia*, computer readable program code that identifies a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject. As discussed above, Gefland fails to teach or suggest identifying a vulnerable portion of the intrinsic spontaneous cardiac cycle of the subject. Applicant respectfully submits that Claims 49 and 51 are patentable over Gefland.

**E. Claim 52**

The Action states that Claim 52 is obvious over Gefland in view of Halperin. Applicant respectfully disagrees. As discussed above, Halperin describes generating an audible alert when proper chest displacement is either not applied or is applied. Halperin fails to teach or suggest the audible alert recited in Claim 52.


### V. New Claims

Claims 54-59 are submitted in order to form a more complete claim set. The claims are supported by the application. As noted above, new Claims 54-57 recite generating an audible alert to advise when to both start and stop compression, as described, for example at page 7 of the pending application. New dependent Claims 58 and 59 are directed to the embodiment described at page 8, lines 4-6 of the pending application.

### VI. Conclusion

Applicant respectfully submits that this application is now in condition for allowance, which action is requested.

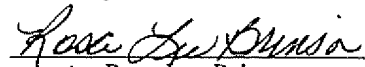
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**CERTIFICATION OF TRANSMISSION  
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I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent and Trademark Office on September 13, 2006.

  
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